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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,537	08/10/2001	Hiroshi Tomiyama	TAN-293	4717

7590 06/16/2004

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413 NORTH WASHINGTON STREET  
ALEXANDRIA, VA 22314

EXAMINER
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HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/925,537	<b>Applicant(s)</b> TOMIYAMA ET AL.	
	<b>Examiner</b> Michael C. Henry	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 8 and 17-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 17-28 is/are rejected.
- 7) ☒ Claim(s) 1-4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### **DETAILED ACTION**

The following office action is a responsive to the Amendment filed, 02/23/04.

The amendment filed 02/23/04 affects the application, 09/925,537 as follows:

1. Claims 1-4 and 17-28 have been amended. Claims 5-7 and 9-16 has been cancelled.

Claim 61 have been added. Claims 8, 29-60 are withdrawn.

2. Applicant responds to the rejection under 35 USC 102(b) and 35 USC 103(a) by amending claims 1-4 and 17-28 and canceling 5-7 and 9-16.

3. Claims 1-4 and 17-28 of Group I are prosecuted by the examiner.

4. The responsive to applicants' arguments is contained herein below.

Claims 1-4, 8 and 17-60 are pending in application

#### ***Claim Objections***

Claims 1-4 are objected to because of the following informalities: The parentheses enclosing the phrase "where z is 0, 1 or 2" implies that this phrase is not necessarily needed in the claim. The examiner respectfully suggests that these parentheses be removed.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 17-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "sialic acid and/or it's derivatives" in claim 1,2,3,4,17-20,22-25, is a term which renders the claims indefinite. This term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art

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would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what chemical derivatives of sialic acid are claimed by applicant, especially in the absence of a how the sialic acid is derivatized. More specifically, in the absence of the specific derivatives of the chemical core claimed (CCC) or distinct language to describe the structural modifications or the chemical names of the derivatives of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of said derivatives that applicant regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims. Therefore, the identity of the sialic acid derivatives is indefinite. Furthermore, the term "its derivatives", in all occurrences is seen to be indefinite where applicant fails to provide how the core compound is modified to obtain some derivatized version of the compound claimed.

***Response to Amendment***

Applicant's arguments with respect to claims 1-4 and 17-28 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

The following is an examiner's statement of reasons for allowance: The examiner has found claims 1-4, 17-28 to be unobvious over the prior art of record and therefore may be allowable over the prior art of record, provided that the objections and 112 rejections are overcome and none of these claims depend on a rejected claim, and provided that the claims are written in an independent acceptable form which includes no new issues. The present invention relates to a compound of a given general formula. The very relevant prior art document to this invention (US 5,977,079) discloses similar compounds of the given formula.

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However, though the compounds of the present invention are similar to the compounds of the prior art, they possess structural differences that are unobvious to those of the prior art.

***Election/Restrictions***

Newly submitted claims 61 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 61 recites the compound of the general formula (1) of claim 1, further comprising a pharmaceutically acceptable carrier conjugated to said compound of the general formula (1). However, the said compound of claim ~~14~~<sup>61</sup> was not originally examined, is a different or distinct invention which would involve a different search.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims ~~14~~<sup>61</sup> is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

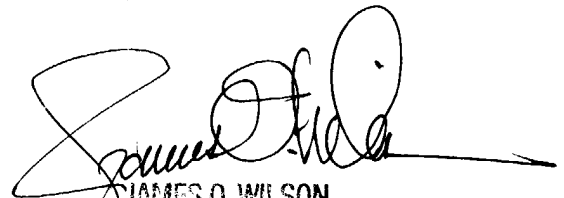
*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

June 14, 2004.



JAMES O. WILSON  
SUPERVISOR  
TECHNICAL CENTER 1600